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(54) **IMPLANT CHARGING FIELD CONTROL THROUGH RADIO LINK**

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USPC 320/108; 607/60, 61
See application file for complete search history.

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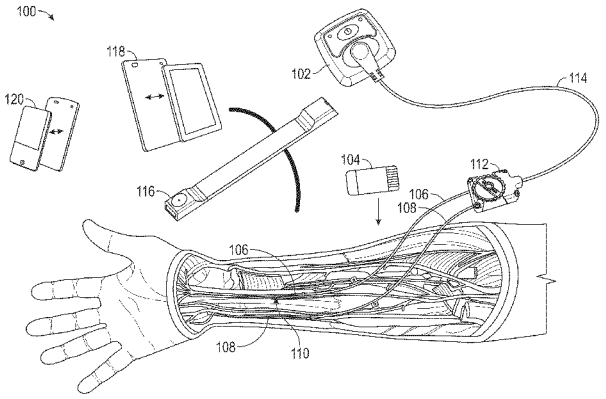
(57) **ABSTRACT**

A charger that evaluates the effectiveness of the charging field generated by the charger at an implantable device. The charger includes a charging coil, a communication module, and a processor. The processor can include instructions to determine the effectiveness of the charging field based on one or several signals or communications received from the implantable device. The charger can use the determination of the effectiveness of the charging field to vary the strength of the charging field and/or to prompt the user to move the charger with respect to the implantable device.

18 Claims, 10 Drawing Sheets



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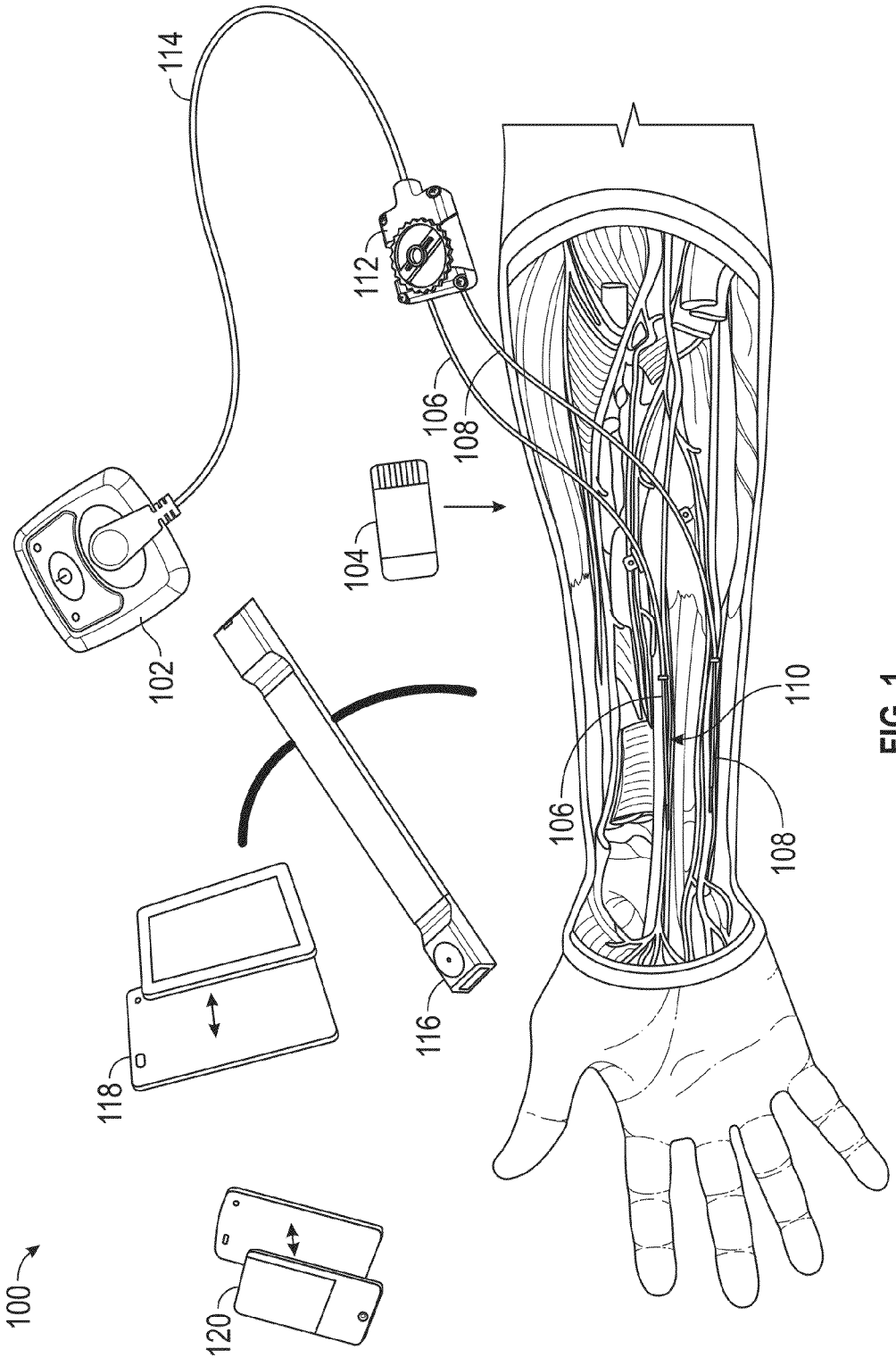

FIG. 1

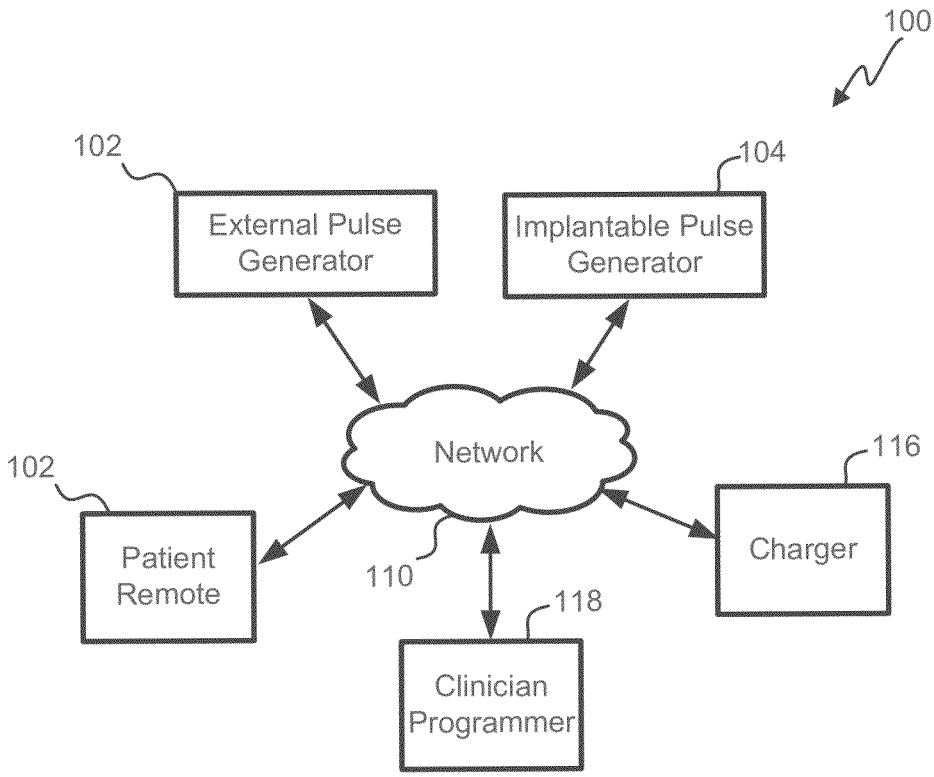
100
102
External Pulse Generator
104
Implantable Pulse Generator
Network
102
Patient Remote
110
116
Charger
118
Clinician Programmer

Fig. 2

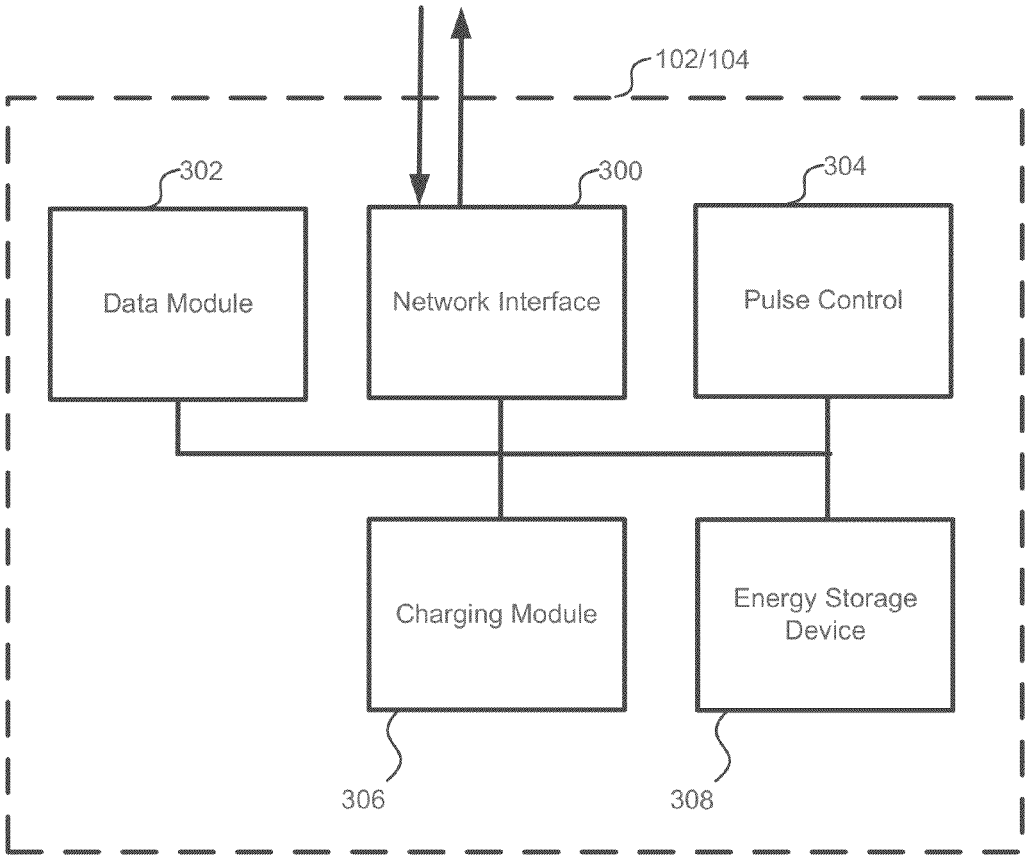
102/104
302
300
304
Data Module
Network Interface
Pulse Control
Charging Module
Energy Storage Device
306
308

Fig. 3

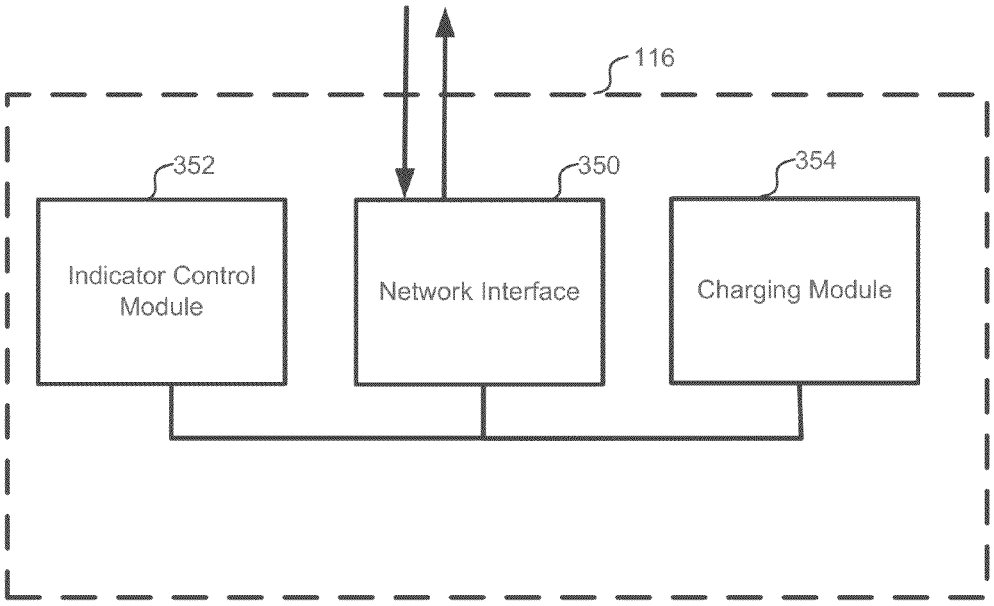
116
352
350
354
Indicator Control Module
Network Interface
Charging Module

Fig. 4

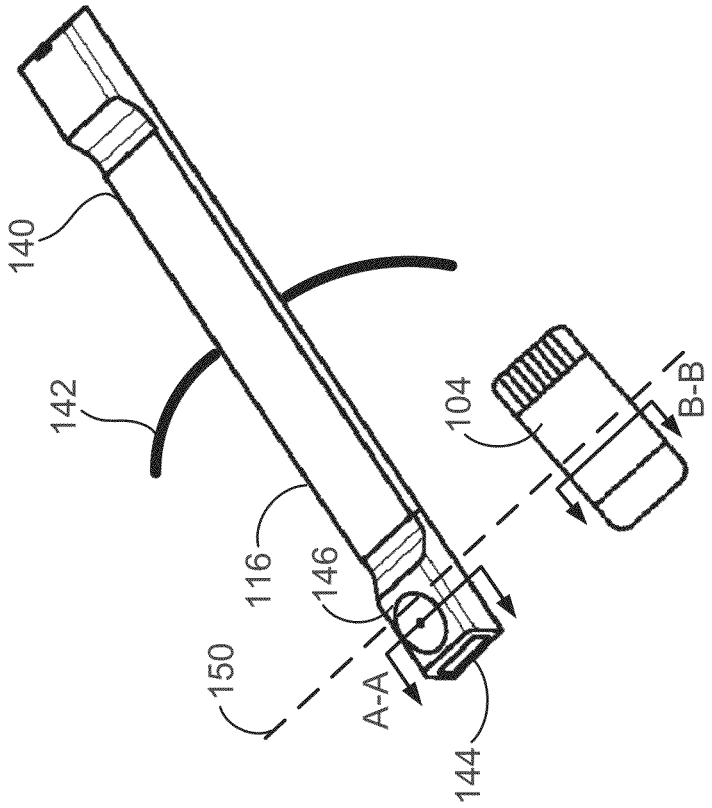

FIG. 5

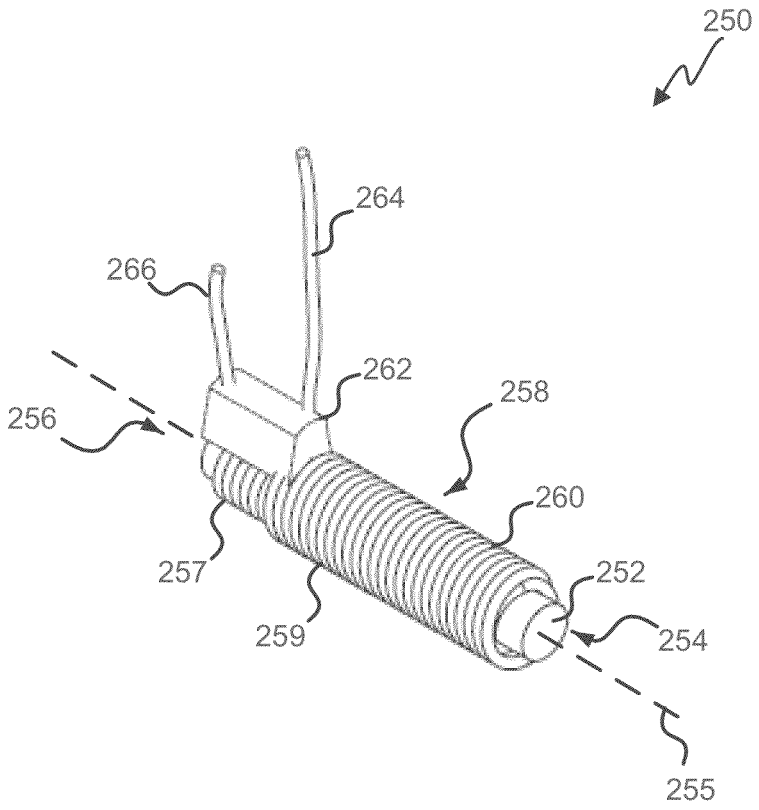

Fig. 6

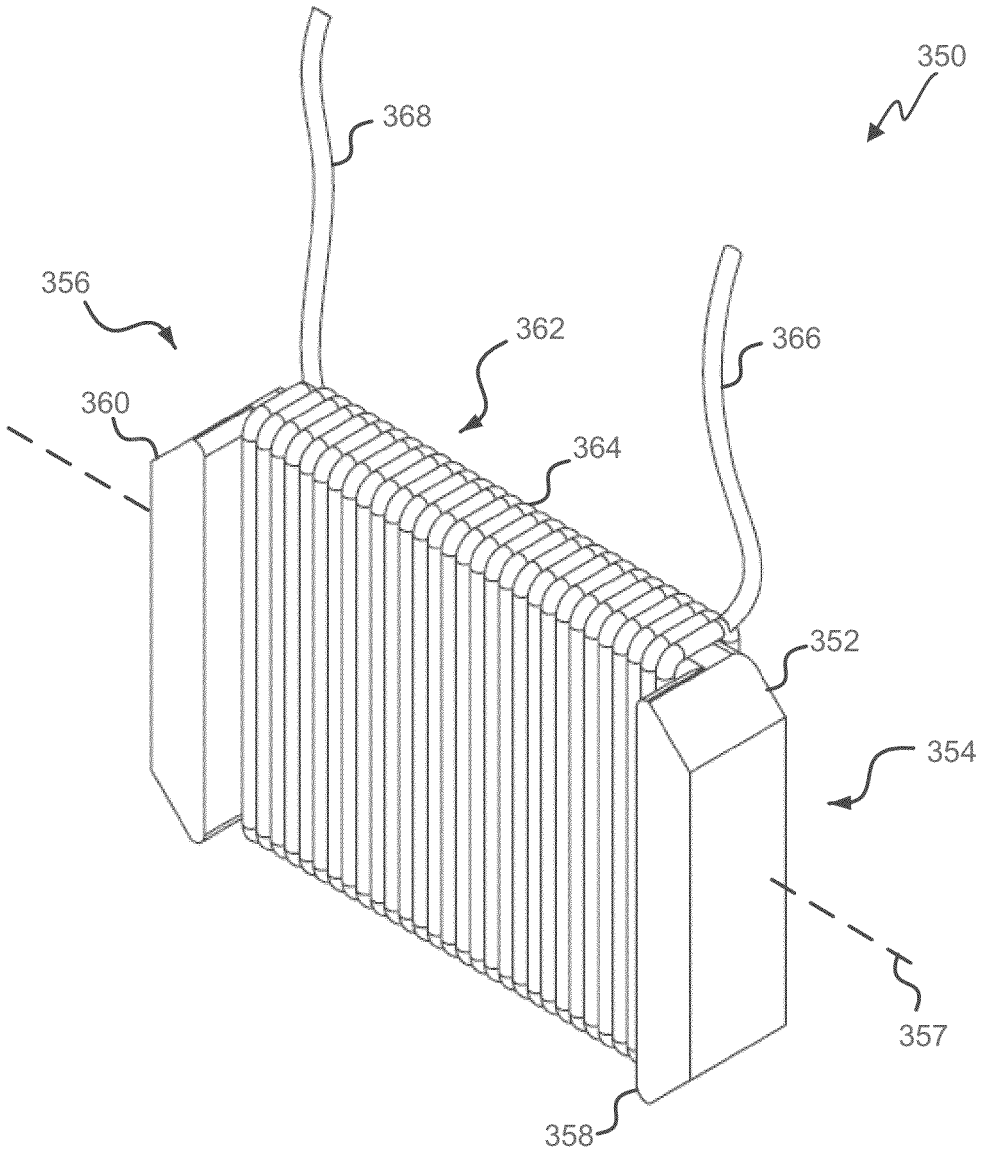

Fig. 7

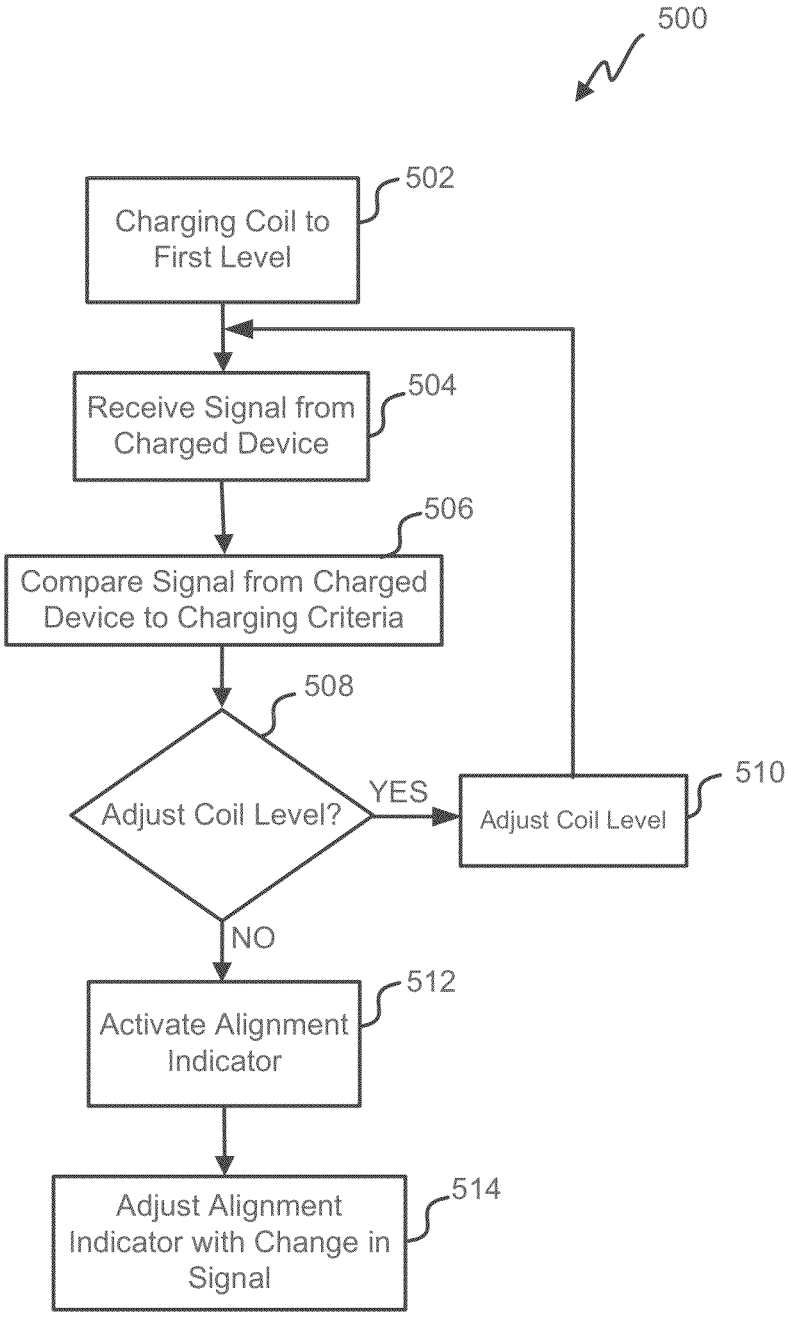
500
Charging Coil to First Level
502
Receive Signal from Charged Device
504
Compare Signal from Charged Device to Charging Criteria
506
Adjust Coil Level?
508
YES
Adjust Coil Level
510
NO
Activate Alignment Indicator
512
Adjust Alignment Indicator with Change in Signal
514

Fig. 8

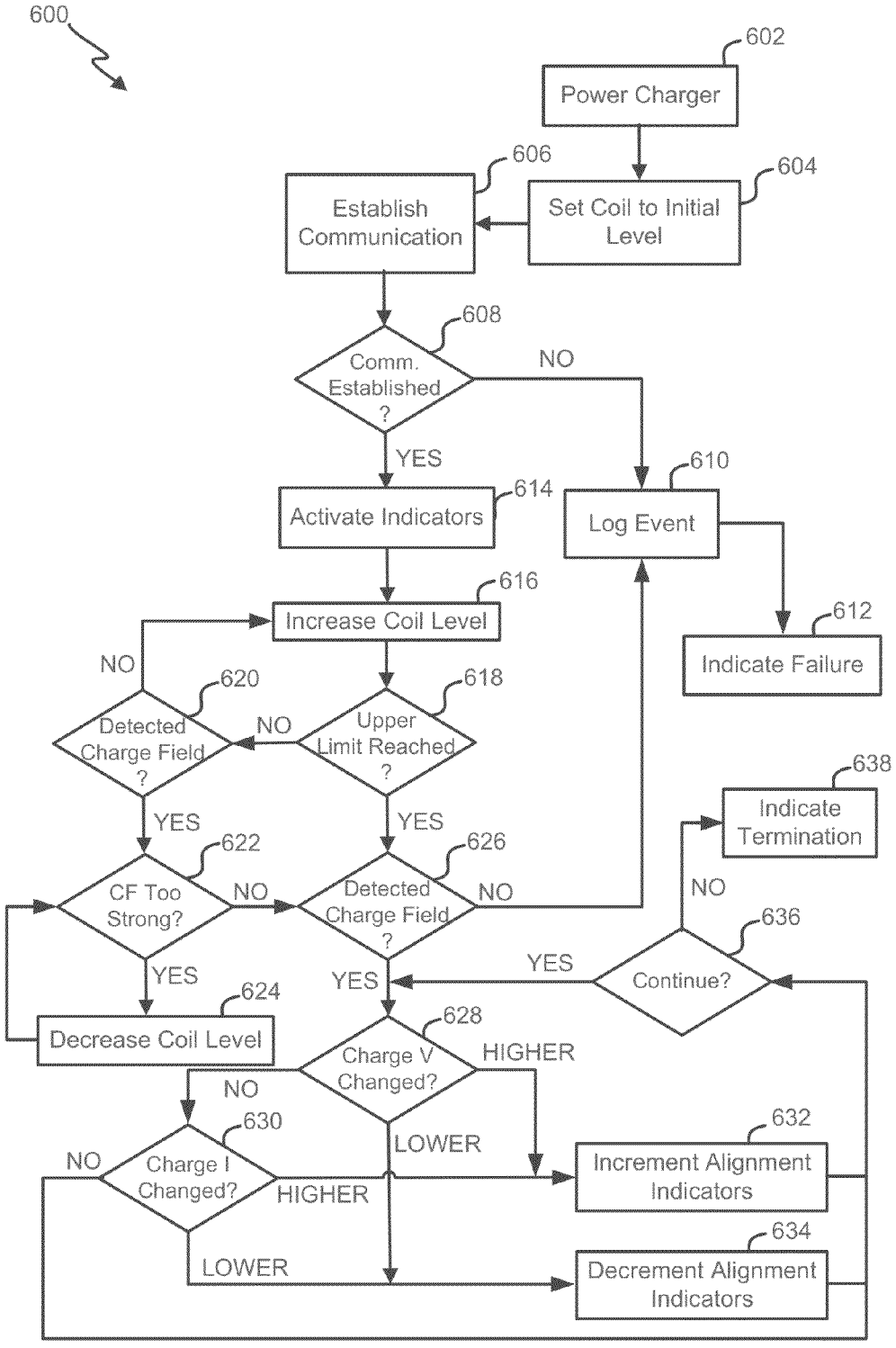
600
602
Power Charger
606
Establish Communication
604
Set Coil to Initial Level
608
Comm. Established ?
NO
YES
610
Log Event
614
Activate Indicators
616
Increase Coil Level
612
Indicate Failure
NO
620
Detected Charge Field ?
NO
618
Upper Limit Reached ?
YES
YES
638
Indicate Termination
622
CF Too Strong?
NO
626
Detected Charge Field ?
NO
NO
636
Continue?
YES
YES
YES
624
Decrease Coil Level
628
Charge V Changed?
HIGHER
NO
630
Charge I Changed?
NO
LOWER
632
Increment Alignment Indicators
HIGHER
LOWER
634
Decrement Alignment Indicators

Fig. 9

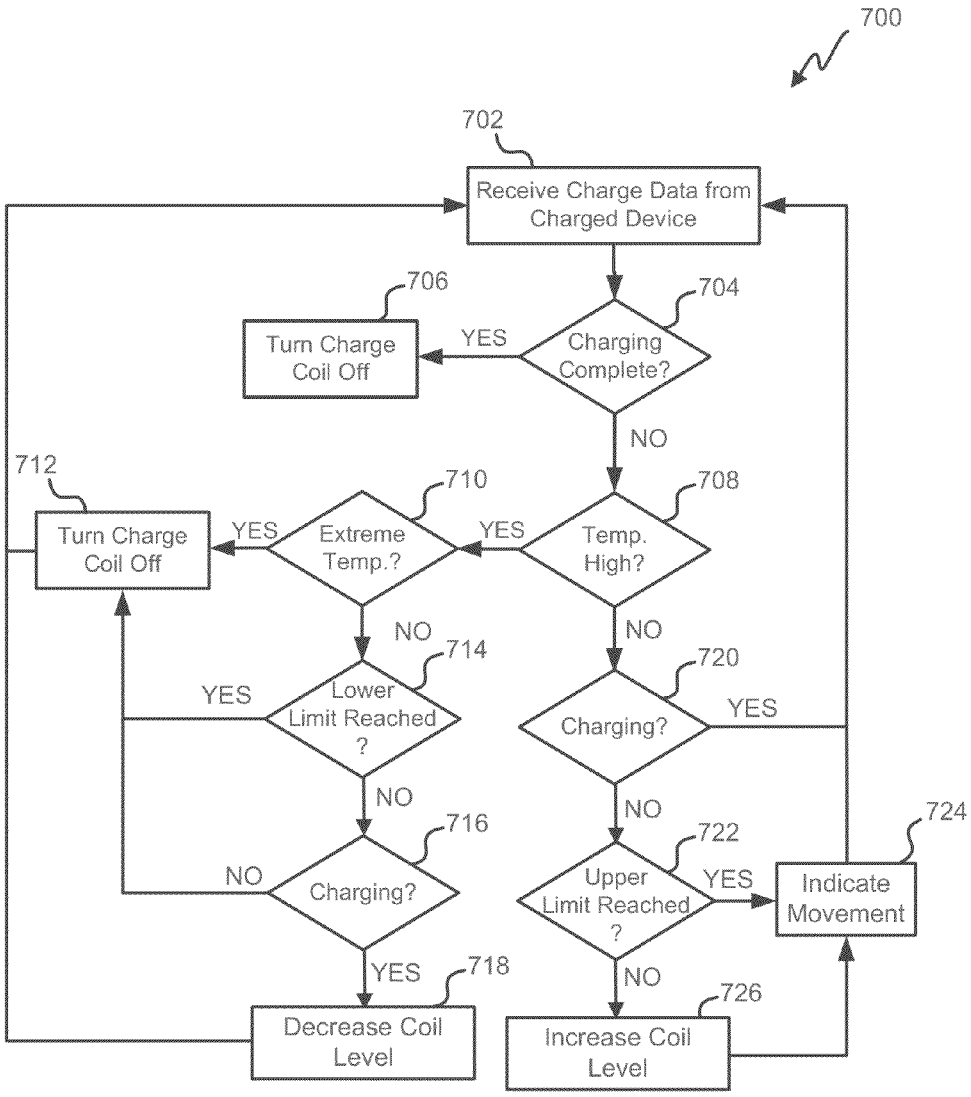
700
702
Receive Charge Data from Charged Device
704
Charging Complete?
YES
706
Turn Charge Coil Off
NO
708
Temp. High?
YES
710
Extreme Temp.?
YES
712
Turn Charge Coil Off
NO
714
Lower Limit Reached ?
YES
NO
716
Charging?
NO
YES
718
Decrease Coil Level
720
Charging?
YES
NO
722
Upper Limit Reached ?
YES
724
Indicate Movement
NO
726
Increase Coil Level

Fig. 10

IMPLANT CHARGING FIELD CONTROL THROUGH RADIO LINK

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/446,280, filed on Jul. 29, 2014, which claims the benefit of U.S. Provisional Application No. 61/859,484 entitled "IMPLANT CHARGING FIELD CONTROL THROUGH RADIO LINK," and filed on Jul. 29, 2013, the entirety of which is hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

The prevalence of use of medical devices in treating ailments is increasing with time. In many instances, and as these medical devices are made smaller, these medical devices are frequently implanted within a patient. While the desirability of implantable devices is increasing as the size of the devices has decreased, the implantation process still frequently requires complicated surgery which can expose the patient to significant risks and protracted recovery times. In light of this, further methods, systems, and devices are desired to increase the ease of use of implantable of medical devices.

BRIEF SUMMARY OF THE INVENTION

One aspect of the present disclosure relates to a charger. The charger can include a charging coil that can magnetically couple with a corresponding charging coil of an implantable device, an indicator that can identify the effectiveness of a charging field created between the charging coil of the charger and the corresponding charging coil of the implantable device, and a processor that can receive a signal from the implantable device at a first time, direct the indicator to identify a first effectiveness level based on a determined effectiveness of the charging field at the first time, receive a signal from the implantable device at a second time, and direct the indicator to identify a second effectiveness level based on a determined effectiveness of the charging field at the second time.

In some embodiments of the charger, the indicator can include one of a visual and an audible indicator. In some embodiments, the visual indicator can include one of a light and a display.

In some embodiments of the charger, the processor determines the effectiveness of the charging field based on at least one of a voltage induced by the charging field at the charging coil of the implantable device and a current induced by the charging field at the charging coil of the implantable device. In some embodiments, the processor can direct the charging coil of the charger to generate a charging field and/or the processor can optimize the charging field before the first time. In some embodiments optimizing of the charging field can include determining if the charging field is inducing a voltage at the charging coil of the implantable device that is greater than the voltage of an energy storage device of the implantable device. In some embodiments, optimizing the charging field can include increasing the voltage on the charging coil of the charger if the charge filed is inducing a voltage at the charging coil of the implantable device that is less than the voltage of an energy storage device of the implantable device.

In some embodiments, the effectiveness of the charging field at the second time is greater than the effectiveness of the charging field at the first time, and in some embodiments, the effectiveness of the charging field at the second time is less than the effectiveness of the charging field at the first time.

One aspect of the present disclosure relates to a method of directing alignment of a charger with an implantable device. The method includes applying a first voltage to a charging coil of a charger, which application of the first voltage to the charging coil of the charger generates a charging field, receiving a first signal from the implantable device at a first time, which first signal includes information identifying a parameter of an effect of the charging field on the implantable device at the first time, directing an indicator to identify a first effectiveness level, receiving a second signal from the implantable device at a second time, which second signal includes information identifying the parameter of the effect of the charging field on the implantable device at the second time, and directing the indicator to identify a second effectiveness level.

In some embodiments directing the indicator to identify the second effectiveness level includes directing the identifier to identify an increased effectiveness when the second effectiveness level is greater than the first effectiveness level. In some embodiments directing the indicator to identify the second effectiveness level includes directing the identifier to identify a decreased effectiveness when the second effectiveness level is less than the first effectiveness level.

In some embodiments, the method includes receiving a third signal from the implantable device at a third time, which third signal includes information identifying a parameter of an effect of the charging field on the implantable device at the third time, and optimizing the voltage applied to the charging coil of the charger based on the third signal. In some embodiments, the receipt of the third signal at the third time precedes the receipt of the first signal at the first time.

In some embodiments, the method includes determining the effectiveness of the charging field at the first time, and determining the effectiveness of the charging field at the second time. In some embodiments, determining the effectiveness of the charging field is based on at least one of a voltage induced by the charging field at the charging coil of the implantable device and a current induced by the charging field at the charging coil of the implantable device. In some embodiments, the effectiveness of the charging field is determined by comparing the parameter of the effect of the charging field on the implantable device with a threshold value. In some embodiments, the charging field is effective if the parameter of the effect of the charging field on the implantable device is greater than the threshold value.

One aspect of the present disclosure relates to a system for delivering power to an implantable device. The system includes an implantable device that includes a network interface, and a charging module having a first charging coil, which charging module can monitor at least one charge parameter. The system can include a charger including a network interface that can receive the at least one charge parameter from the implantable device, a charging module including a second charging coil, which charging module can control the voltage of the second charging coil according to the received at least one charge parameter, and an indicator control module that can control an indicator to identify the effectiveness of the magnetic coupling between the implantable device and the charger.

In some embodiments, the indicator can identify the effectiveness of the magnetic coupling between the implantable device and the charger by identifying a change in the least one charge parameter over a period of time. In some embodiments the at least one charge parameter includes a voltage induced at the first charging coil. In some embodiments the at least one charge parameter includes a current induced at the charging coil of the implantable device.

One aspect of the present disclosure relates to a charger. The charger includes a charging coil that can magnetically couple with a corresponding charging coil of a peripherally implanted pulse generator, which peripherally implanted pulse generator includes a plurality of electrodes, an indicator that can identify the effectiveness of a charging field created between the charging coil of the charger and the corresponding charging coil of the implantable device, and a processor that can receive a signal from the peripherally implanted pulse generator at a first time, which signal indicates the effectiveness of the charging field at the first time, direct the indicator to identify a first effectiveness level, receive a signal from the peripherally implanted pulse generator at a second time, which signal indicates the effectiveness of the charging field at the second time, and direct the indicator to identify a second effectiveness level.

One aspect of the present disclosure relates to a charger. The charger includes a charging coil that can magnetically couple with a corresponding charging coil of recharging device, an indicator that can identify the effectiveness of a charging field created between the charging coil of the charger and the corresponding charging coil of the recharging device, and a processor that can receive a signal from the recharging device at a first time, direct the indicator to identify a first effectiveness level based on a determined effectiveness of the charging field at the first time, receive a signal from the recharging device at a second time, and direct the indicator to identify a second effectiveness level based on a determined effectiveness of the charging field at the second time.

In some embodiments, the recharging device is an implantable device. In some embodiments, the implantable device can be a peripherally implanted pulse generator including a plurality of electrodes

Further areas of applicability of the present disclosure will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating various embodiments, are intended for purposes of illustration only and are not intended to necessarily limit the scope of the disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic illustration of one embodiment of an implantable neurostimulation system.

FIG. **2** is a schematic illustration of one embodiment of interconnectivity of the implantable neurostimulation system.

FIG. **3** is a schematic illustration of one embodiment of the architecture of the external pulse generator and/or of the implantable pulse generator that is a part of the implantable neurostimulation system.

FIG. **4** is a schematic illustration of one embodiment of the charger that is a part of the implantable neurostimulation system.

FIG. **5** is a perspective view of one embodiment of an implantable pulse generator and a charger.

FIG. **6** is a perspective view of one embodiment of a charging coil that can be used in an implantable pulse generator.

FIG. **7** is a perspective view of one embodiment of a charging coil that can be used in a charger.

FIG. **8** is a flowchart illustrating one embodiment of a process for providing an alignment indicator for a charger.

FIG. **9** is a flowchart illustrating one embodiment of a process for providing an alignment indicator for a charger based on detected variations in measured voltage and current.

FIG. **10** is a flowchart illustrating one embodiment of a process in which movement of a charger is detected during the charging process.

In the appended figures, similar components and/or features may have the same reference label. Where the reference label is used in the specification, the description is applicable to any one of the similar components having the same reference label.

DETAILED DESCRIPTION OF THE INVENTION

A significant percentage of the Western (EU and US) population is affected by Neuropathic pain (chronic intractable pain due to nerve damage). In many people, this pain is severe. There are thousands of patients that have chronic intractable pain involving a nerve. Neuropathic pain can be very difficult to treat with only half of patients achieving partial relief. Thus, determining the best treatment for individual patients remains challenging. Conventional treatments include certain antidepressants, anti-epileptic drugs and opioids. However, side effects from these drugs can be detrimental. In some of these cases, electrical stimulation can provide effective treatment of this pain without the drug-related side effects.

A spinal cord stimulator is a device used to deliver pulsed electrical signals to the spinal cord to control chronic pain. Because electrical stimulation is a purely electrical treatment and does not cause side effects similar to those caused by drugs, an increasing number of physicians and patients favor the use of electrical stimulation over drugs as a treatment for pain. The exact mechanisms of pain relief by spinal cord stimulation (SCS) are unknown. Early SCS trials were based on the Gate Control Theory, which posits that pain is transmitted by two kinds of afferent nerve fibers. One is the larger myelinated Aδ fiber, which carries quick, intense-pain messages. The other is the smaller, unmyelinated "C" fiber, which transmits throbbing, chronic pain messages. A third type of nerve fiber, called Aβ, is "non-nociceptive," meaning it does not transmit pain stimuli. The gate control theory asserts that signals transmitted by the Aδ and C pain fibers can be thwarted by the activation/stimulation of the non-nociceptive Aβ fibers and thus inhibit an individual's perception of pain. Thus, neurostimulation provides pain relief by blocking the pain messages before they reach the brain.

SCS is often used in the treatment of failed back surgery syndrome, a chronic pain syndrome that has refractory pain due to ischemia. SCS complications have been reported in a large portion, possibly 30% to 40%, of all SCS patients. This increases the overall costs of patient pain management and decreases the efficacy of SCS. Common complications include: infection, hemorrhaging, injury of nerve tissue, placing device into the wrong compartment, hardware malfunction, lead migration, lead breakage, lead disconnection, lead erosion, pain at the implant site, generator overheating, and charger overheating. The occurrence rates of common complications are surprisingly high: including lead extension connection issues, lead breakage, lead migration and infection.

Peripheral neuropathy, another condition that can be treated with electrical stimulation, may be either inherited or acquired. Causes of acquired peripheral neuropathy include physical injury (trauma) to a nerve, viruses, tumors, toxins, autoimmune responses, nutritional deficiencies, alcoholism, diabetes, and vascular and metabolic disorders. Acquired peripheral neuropathies are grouped into three broad categories: those caused by systemic disease, those caused by trauma, and those caused by infections or autoimmune disor-

ders affecting nerve tissue. One example of an acquired peripheral neuropathy is trigeminal neuralgia, in which damage to the trigeminal nerve (the large nerve of the head and face) causes episodic attacks of excruciating, lightning-like pain on one side of the face.

A high percentage of patients with peripheral neuropathic pain do not benefit from SCS for various reasons. However, many of these patients can receive acceptable levels of pain relief via direct electrical stimulation to the corresponding peripheral nerves. This therapy is called peripheral nerve stimulation (PNS). As FDA approved PNS devices have not been commercially available in the US market, Standard spinal cord stimulator (SCS) devices are often used off label by pain physicians to treat this condition. A significant portion of SCS devices that have been sold may have been used off-label for PNS.

As current commercially-available SCS systems were designed for stimulating the spinal cord and not for peripheral nerve stimulation, there are more device complications associated with the use of SCS systems for PNS than for SCS. Current SCS devices (generators) are large and bulky. In the event that an SCS is used for PNS, the SCS generator is typically implanted in the abdomen or in the lower back above the buttocks and long leads are tunneled across multiple joints to reach the target peripheral nerves in the arms, legs or face. The excessive tunneling and the crossing of joints leads to increased post-surgical pain and higher device failure rates. Additionally, rigid leads can lead to skin erosion and penetration, with lead failure rates being far too high within the first few years of implantation. Many or even most complications result in replacement surgery and even multiple replacement surgeries in some cases.

One embodiment of an implantable neurostimulation system **100** is shown in FIG. **1**, which implantable neurostimulation system **100** can be, for example, a peripherally-implantable neurostimulation system **100**. In some embodiments, the implantable neurostimulation system **100** can be used in treating patients with, for example, chronic, severe, refractory neuropathic pain originating from peripheral nerves. In some embodiments, the implantable neurostimulation system **100** can be used to either stimulate a target peripheral nerve or the posterior epidural space of the spine.

The implantable neurostimulation system **100** can include one or several pulse generators. The pulse generators can comprise a variety of shapes and sizes, and can be made from a variety of materials. In some embodiments, the one or several pulse generators can generate one or several non-ablative electrical pulses that are delivered to a nerve to control pain. In some embodiments, these pulses can have a pulse amplitude of between 0-1,000 mA, 0-100 mA, 0-50 mA, 0-25 mA, and/or any other or intermediate range of amplitudes. One or more of the pulse generators can include a processor and/or memory. In some embodiments, the processor can provide instructions to and receive information from the other components of the implantable neurostimulation system **100**. The processor can act according to stored instructions, which stored instructions can be located in memory, associated with the processor, and/or in other components of the implantable neurostimulation system **100**. The processor can, in accordance with stored instructions, make decisions. The processor can comprise a microprocessor, such as a microprocessor from Intel® or Advanced Micro Devices, Inc.®, or the like.

In some embodiments, the stored instructions directing the operation of the processor may be implemented by hardware, software, scripting languages, firmware, middleware, microcode, hardware description languages, and/or any combination thereof. When implemented in software, firmware, middleware, scripting language, and/or microcode, the program code or code segments to perform the necessary tasks may be stored in a machine readable medium such as a storage medium. A code segment or machine-executable instruction may represent a procedure, a function, a subprogram, a program, a routine, a subroutine, a module, a software package, a script, a class, or any combination of instructions, data structures, and/or program statements. A code segment may be coupled to another code segment or a hardware circuit by passing and/or receiving information, data, arguments, parameters, and/or memory contents. Information, arguments, parameters, data, etc. may be passed, forwarded, or transmitted via any suitable means including memory sharing, message passing, token passing, network transmission, etc.

In some embodiments, the memory of one or both of the pulse generators can be the storage medium containing the stored instructions. The memory may represent one or more memories for storing data, including read only memory (ROM), random access memory (RAM), magnetic RAM, core memory, magnetic disk storage mediums, optical storage mediums, flash memory devices and/or other machine readable mediums for storing information. In some embodiments, the memory may be implemented within the processor or external to the processor. In some embodiments, the memory can be any type of long term, short term, volatile, nonvolatile, or other storage medium and is not to be limited to any particular type of memory or number of memories, or type of media upon which memory is stored. In some embodiments, the memory can include, for example, one or both of volatile and nonvolatile memory. In one specific embodiment, the memory can include a volatile portion such as RAM memory, and a nonvolatile portion such as flash memory.

In some embodiments, one of the pulse generators can be an external pulse generator **102** or an implantable pulse generator **104**. While frequently referred to herein as an implantable pulse generator **104**, this can also include an implantable device recharging device. The external pulse generator **102** can be used to evaluate the suitability of a patient for treatment with the implantable neurostimulation system **100** and/or for implantation of an implantable pulse generator **104**.

In some embodiments, one of the pulse generators can be the implantable pulse generator **104**, which can be sized and shaped, and made of material to allow implantation of the implantable pulse generator **104** inside of a body. In some embodiments, the implantable pulse generator **104** can be sized and shaped so as to allow placement of the implantable pulse generator **104** at any desired location in a body, and in some embodiments, placed proximate to a peripheral nerve such that leads (discussed below) are not tunneled across joints and/or such that extension cables are not needed.

The implantable pulse generator **104** can include one or several energy storage features. In some embodiments, these features can be configured to store energy, such as, for example, electric energy, that can be used in the operation of the implantable pulse generator **104**. These energy storage features can include, for example, one or several batteries, including rechargeable batteries, one or several capacitors, one or several fuel cells, or the like.

In some embodiments, the electrical pulses generated by the pulse generator can be delivered to one or several nerves **110** and/or to tissue proximate to one or several nerves **110** via one or several leads. The leads can include conductive portions, such as electrodes or contact portions of electrodes, and non-conductive portions. The leads can have a variety of shapes, can be a variety of sizes, and can be made from a variety of materials, which size, shape, and materials can be

dictated by the application or other factors. In some embodiments, the leads can be implanted proximate to a peripheral nerve. In one embodiment, both the implantable pulse generator **104** and the leads can be implanted in a peripheral portion of the patient's body, and can be configured to deliver one or several electrical pulses to the peripheral nerve.

In some embodiments, the leads can include an anodic lead **106** and/or a cathodic lead **108**. In some embodiments, the anodic lead **106** and the cathodic lead **108** can be identical leads, but can receive pulses of different polarity from the pulse generator.

In some embodiments, the leads can connect directly to the pulse generator, and in some embodiments, the leads can be connected to the pulse generator via a connector **112** and a connector cable **114**. The connector **112** can comprise any device that is able to electrically connect the leads to the connector cable **114**. Likewise, the connector cable can be any device capable of transmitting distinct electrical pulses to the anodic lead **106** and the cathodic lead **108**.

In some embodiments, the implantable neurostimulation system **100** can include a charger **116** that can be configured to recharge the implantable pulse generator **104** when the implantable pulse generator **104** is implanted within a body. The charger **116** can comprise a variety of shapes, sizes, and features, and can be made from a variety of materials. Like the pulse generators **102**, **104**, the charger **116** can include a processor and/or memory having similar characteristics to those discussed above. In some embodiments, the charger **116** can recharge the implantable pulse generator **104** via an inductive coupling.

In some embodiments, one or several properties of the electrical pulses can be controlled via a controller. In some embodiments, these properties can include, for example, the frequency, strength, pattern, duration, or other aspects of the timing and magnitude of the electrical pulses. In one embodiment, these properties can include, for example, a voltage, a current, or the like. In one embodiment, a first electrical pulse can have a first property and a second electrical pulse can have a second property. This control of the electrical pulses can include the creation of one or several electrical pulse programs, plans, or patterns, and in some embodiments, this can include the selection of one or several pre-existing electrical pulse programs, plans, or patterns. In the embodiment depicted in FIG. **1**, the implantable neurostimulation system **100** includes a controller that is a clinician programmer **118**. The clinician programmer **118** can be used to create one or several pulse programs, plans, or patterns and/or to select one or several of the created pulse programs, plans, or patterns. In some embodiments, the clinician programmer **118** can be used to program the operation of the pulse generators including, for example, one or both of the external pulse generator **102** and the implantable pulse generator **104**. The clinician programmer **118** can comprise a computing device that can wiredly and/or wirelessly communicate with the pulse generators. In some embodiments, the clinician programmer **118** can be further configured to receive information from the pulse generators indicative of the operation and/or effectiveness of the pulse generators and the leads.

In some embodiments, the controller of the implantable neurostimulation system **100** can include a patient remote **120**. The patient remote **120** can comprise a computing device that can communicate with the pulse generators via a wired or wireless connection. The patient remote **120** can be used to program the pulse generator, and in some embodiments, the patient remote **120** can include one or several pulse generation programs, plans, or patterns created by the clinician programmer **118**. In some embodiments, the patient remote **120** can be used to select one or several of the pre-existing pulse generation programs, plans, or patterns and to select, for example, the duration of the selected one of the one or several pulse generation programs, plans, or patterns.

Advantageously, the above outlined components of the implantable neurostimulation system **100** can be used to control and provide the generation of electrical pulses to mitigate patient pain.

With reference now to FIG. **2**, a schematic illustration of one embodiment of interconnectivity of the implantable neurostimulation system **100** is shown. As seen in FIG. **2**, several of the components of the implantable neurostimulation system **100** are interconnected via network **110**. In some embodiments, the network **110** allows communication between the components of the implantable neurostimulation system **100**. The network **110** can be, for example, a local area network (LAN), a wide area network (WAN), a wired network, a custom network, wireless network, a telephone network such as, for example, a cellphone network, the Internet, the World Wide Web, or any other desired network or combinations of different networks. In some embodiments, the network **110** can use any desired communication and/or network protocols. The network **110** can include any communicative interconnection between two or more components of the implantable neurostimulation system **100**. In one embodiment, the communications between the devices of the implantable neurostimulation system **100** can be according to any communication protocol including, for example those covered by Near Field Communication (NFC), Bluetooth, or the like. In some embodiments, different components of the system may utilize different communication networks and/or protocols.

With reference now to FIG. **3**, a schematic illustration of one embodiment of the architecture of the external pulse generator **102** and/or of the implantable pulse generator **104** is shown. In some embodiments, each of the components of the architecture of the one of the pulse generators **102**, **104** can be implemented using the processor, memory, and/or other hardware component of the one of the pulse generators **102**, **104**. In some embodiments, the components of the architecture of the one of the pulse generators **102**, **104** can include software that interacts with the hardware of the one of the pulse generators **102**, **104** to achieve a desired outcome.

In some embodiments, the pulse generator **102**/**104** can include, for example, a network interface **300**, or alternatively, a communication module. The network interface **300**, or alternatively, the communication module, can be configured to access the network **110** to allow communication between the pulse generator **102**, **104** and the other components of the implantable neurostimulation system **100**. In some embodiments, the network interface **300**, or alternatively, a communication module, can include one or several antennas and software configured to control the one or several antennas to send information to and receive information from one or several of the other components of the implantable neurostimulation system **100**.

The pulse generator **102**, **104** can further include a data module **302**. The data module **302** can be configured to manage data relating to the identity and properties of the pulse generator **102**, **104**. In some embodiments, the data module can include one or several databases that can, for example, include information relating to the pulse generator **102**, **104** such as, for example, the identification of the pulse generator, one or several properties of the pulse generator **102**, **104**, or the like. In one embodiment, the data identifying the pulse generator **102**, **104** can include, for example, a serial number of the pulse generator **102**, **104** and/or other identifier of the pulse generator **102**, **104** including, for example, a unique

identifier of the pulse generator **102**, **104**. In some embodiments, the information associated with the property of the pulse generator **102**, **104** can include, for example, data identifying the function of the pulse generator **102**, **104**, data identifying the power consumption of the pulse generator **102**, **104**, data identifying the charge capacity of the pulse generator **102**, **104** and/or power storage capacity of the pulse generator **102**, **104**, data identifying potential and/or maximum rates of charging of the pulse generator **102**, **104**, and/or the like.

The pulse generator **102**, **104** can include a pulse control **304**. In some embodiments, the pulse control **304** can be configured to control the generation of one or several pulses by the pulse generator **102**, **104**. In some embodiments, for example, this information can identify one or several pulse patterns, programs, or the like. This information can further specify, for example, the frequency of pulses generated by the pulse generator **102**, **104**, the duration of pulses generated by the pulse generator **102**, **104**, the strength and/or magnitude of pulses generated by the pulse generator **102**, **104**, or any other details relating to the creation of one or several pulses by the pulse generator **102**, **104**. In some embodiments, this information can specify aspects of a pulse pattern and/or pulse program, such as, for example, the duration of the pulse pattern and/or pulse program, and/or the like. In some embodiments, information relating to and/or for controlling the pulse generation of the pulse generator **102**, **104** can be stored within the memory.

The pulse generator **102**, **104** can include a charging module **306**. In some embodiments, the charging module **306** can be configured to control and/or monitor the charging/recharging of the pulse generator **102**, **104**. In some embodiments, for example, the charging module **306** can include one or several features configured to receive energy for recharging the pulse generator **102**, **104** such as, for example, one or several inductive coils/features that can interact with one or several inductive coils/features of the charger **116** to create an inductive coupling to thereby recharge the pulse generator **102**, **104**.

In some embodiments, the charging module **306** can include hardware and/or software configured to monitor the charging of the pulse generator **102**, **104**. In some embodiments, the hardware can include, for example, a charging coil configured to magnetically couple with a charging coil of the charger **116**. In some embodiments, these features can be configured to monitor the temperature of one or several components of the pulse generator **102**, **104**, the rate of charge of the pulse generator **102**, **104**, the charge state of the pulse generator **102**, **104**, or the like. These features can include, for example, one or several resistors, thermistors, thermocouples, temperature sensors, current sensors, charge sensors, or the like. In some embodiments, the charging module **306** can be configured to monitor, for example, voltage of the energy storage features, current flowing through, for example, a shunt circuit configured to channel excess current, one or several temperatures of, for example, the energy storage features and/or of the pulse generator **102**, **104**, the presence of a detectable charging field, the charge state of the energy storage features, and/or the like. In some embodiments, the one or several parameters can be provided to the network interface **300**, and communicated via network **114** to other components of the implantable neurostimulation system **100**.

The pulse generator **102**, **104** can include an energy storage device **308**. The energy storage device **308**, which can include the energy storage features, can be any device configured to store energy and can include, for example, one or several batteries, capacitors, fuel cells, or the like. In some embodiments, the energy storage device **308** can be configured to receive charging energy from the charging module **306**.

With reference now to FIG. **4**, a schematic illustration of one embodiment of the charger **116** is shown. In some embodiments, each of the components of the architecture of the charger **116** can be implemented using the processor, memory, and/or other hardware component of the charger **116**. In some embodiments, the components of the architecture of the charger **116** can include software that interacts with the hardware of the charger **116** to achieve a desired outcome.

In some embodiments, the charger **116** can include, for example, a network interface **350**, or alternatively, a communication module. The network interface **350**, or alternatively, a communication module, can be configured to access the network **110** to allow communication between the charger **116** and the other components of the implantable neurostimulation system **100**. In some embodiments, the network interface **350**, or alternatively, a communication module, can include one or several antennas and software configured to control the one or several antennas to send information to and receive information from one or several of the other components of the implantable neurostimulation system **100**.

In some embodiments, the charger **116** can include an indicator control module **352**. In some embodiments, the indicator control module **352** can be configured to receive data relating to one or several parameters measured at the implantable pulse generator **104**. The indicator control module **352** can use this information to determine whether charging would be improved by repositioning and/or reorienting of the charger **116** with respect to the implantable pulse generator **104**. In some embodiments, this determination can include determining the relative effectiveness of the charging at a second, current position as compared to a first, previous position, and controlling the indicator to indicate increased charging effectiveness if the charging is more effective at the second position than and the first position, or similarly controlling the indicator to indicate the decreased charging effectiveness if the charging is less effective at the second position than at the first position. In some embodiments, this can include comparing the data received from the implantable pulse generator **104** to stored data to determine whether the charging effectiveness of the current position of the charger **116** is sufficient or insufficient. In the event that the charging effectiveness is insufficient, then the indicator control module **352** can be configured to control the indicator to indicate this insufficiency of the charging effectiveness. Similarly, in the event that the charging effectiveness is sufficient, then the indicator control module **352** can be configured to control the indicator to indicate this sufficiency of the charging effectiveness.

The charger **116** can include a charging module **354**. The charging module **354** can be configured to control and/or monitor the charging of one or several of the pulse generators **102**, **104**. In some embodiments, for example, the charging module **354** can include one or several protocols that can request information from the one or several pulse generators **102**, **104** at one or several times before, during, and after charging. This information can be received by the charger **116** from the pulse generator **102**, **104** and can be used to control the generation of and/or properties of the charging field. In some embodiments, the charging module **354** can include one or several features configured to transmit energy charging coils that can magnetically couple with the charging coil of the pulse generator **102**, **104** to thereby recharge the pulse generator **102**, **104**.

In some embodiments, the charging module **354** can be configured to power the charging coil of the charger **116** at any desired power level across a continuous power spectrum, and in some embodiments, the charging module **354** can be configured to power the charging coil of the charger **116** at one of several discrete power levels across a digitized power spectrum. In one such embodiment, for example, the charging module can be configured to power the charging coil of the charger **116** at one of 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 50, 100, or any other or intermediate discrete power levels.

With reference now to FIG. **5**, a perspective view of one embodiment of the implantable pulse generator **104** and the charger **116** is shown. The charger **116** includes an elongate body **140**. The elongate body **140** can be configured to be placed against the body of the patient such as, for example, directly against the skin of the patient, and/or proximate to the skin of the patient such as, for example, against a piece of clothing or apparel worn by the patient.

In some embodiments, the charger **116** can include at least one retention feature **142** that can be configured to hold the elongate body **140** in a desired position against the patient's body. In some embodiments, the retention feature **142** can be, for example, a strap, a band, or the like. In one such embodiment, for example, in which the charger **116** is placed on a portion of the body, such as, for example, the neck, torso, or limb, including, one of a leg, a foot, an arm, and a hand, the retention feature **142** can secure the charger **116** to that portion of the body and can secure the position and orientation of the charger **116** with respect to that portion of the body. In some embodiments, the retention feature **142** can be configured to hold the elongate body **140** of the charger **116** in a constant orientation with respect to the body of the patient. In some embodiments, a constant orientation may include some variations of the orientation of the elongate body **140** described by an angle measured from a longitudinal axis of the elongate body **140** in a first position to the longitudinal axis of the elongate body **140** in a second position. In some embodiments, this angle can be, for example, 1 degree, 5 degrees, 10 degrees, 15 degrees, 20 degrees, 30 degrees, 40 degrees, or any other or intermediate angle.

The charger **116** can include a charge head **144**. The charge head **144** can include one or several features to facilitate the charging of the implantable pulse generator **104**. In some embodiments, these features can include, for example, the charge head charging coil that will be discussed at greater length below.

As seen in FIG. **5**, the charge head **144** includes a rotatable mount **146**. In some embodiments, the rotatable mount **146** can be connected to the charging coil of the charge head **144** and can be configured to allow the rotation of the charging coil. The rotatable mount can include one or several features that can facilitate the rotation/re-orientation of the rotatable mount. These can include, for example, a feature configured to engage with, for example, a key, a screwdriver, a wrench, or the like, one or several features configured to facilitate digital manipulation such as, for example, one or several knurls, grips, or the like, or any other feature. In some embodiments, for example, the rotatable mount **146** can be configured to allow the manipulation of the angular position of the charge head charging coil with respect to, for example, the longitudinal axis of the elongate member **140**.

As further seen in FIG. **5**, the implantable pulse generator **104** can be positioned with respect to the charger **116** to allow recharging of the implantable pulse generator **104**. In some embodiments, the implantable pulse generator **104** can be positioned so as to be within an effective distance or range from the charger **116**. In some embodiments, this distance can be such that recharging of the implantable pulse generator **104** is effective, and the distance can be, for example, within 10 cm of the charge head **144**, 5 cm of the charge head **144**, 4 cm of the charge head **144**, 3 cm of the charge head **144**, 2 cm of the charge head **144**, 1 cm of the charge head **144**, 0.5 cm of the charge head **144**, 0.1 cm of the charge head **144**, and/or any other or intermediate distance from the charge head **144**. In some embodiments, the implantable pulse generator **104** can be positioned such that the implantable pulse generator **104** is directly below the charge head **144** of the charger **116**. This positioning is indicated in FIG. **5** by axis **150**. Alternatively, in some embodiments, implantable pulse generator **104** can be positioned so as to not be directly below the charge head **144** of charger **116**.

With reference now to FIG. **6**, a perspective view of one embodiment of a charging coil **250** that can be used in the implantable pulse generator **104** is shown. The charging coil **250** can comprise a variety of shapes and sizes and can be made of a variety of materials. The charging coil can comprise a solenoid. In some embodiments, the charging coil **250** can be sized and shaped so as to fit within the implantable pulse generator **104**, and specifically inside of a housing of the implantable pulse generator **104**. In one embodiment, for example, the charging coil can be positioned proximate to a surface of the housing such that no other components of the implantable pulse generator **104** are between the charging coil **250** and this surface. In some embodiments, the implantable pulse generator **104** can be implanted such that this surface is proximate to the skin of the patient and/or the relatively more proximate to the skin of the patient than other portions of the implantable pulse generator.

In some embodiments, the charging coil **250** can be configured to magnetically couple with features of the charger **116** such as, for example, a charging coil of the charger **116** to recharge the one or several energy storage features of the implantable pulse generator **104**.

In some embodiments, and to facilitate the magnetic coupling of the charging coil **250** of the implantable pulse generator **104** with the charging coil of the charger **116**, the charging coil **250** of the implantable pulse generator **104** can have a high Q factor. In some embodiments, for example, the Q factor of the charging coil **250** can be, for example, at least 10, at least 20, at least 30, at least 40, at least 50, at least 60, at least 70, at least 80, at least 100, at least 120, at least 200, and/or any other or intermediate value.

The charging coil **250** can include a core **252**. The core **252** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the core **252** can be sized and shaped to facilitate the wrapping of one or several wires around the core **252** and/or the core **252** can be sized and shaped to achieve and/or facilitate in achieving a desired Q factor for the charging coil **250**. In some embodiments, the core **252** can comprise a ferritic core, and in some embodiments, the core **252** can comprise a soft ferritic core.

In some embodiments, and as shown in FIG. **6**, the core **252** can comprise an elongate member, and can specifically comprise an elongate cylindrical member that can have, a distal, first end **254** and a proximal, second end **256**. As seem in FIG. **6**, an axis **255**, which can be a longitudinal axis, can extend along the centerline of the core **252** between the first end **254** and the second end **256**, and the length of the core **252** can be measured and/or defined with respect to this axis **255**. In some embodiments, the length of the core **252** can be, for example, approximately 0.1 inches, 0.2 inches, 0.3 inches, 0.4 inches, 0.5 inches, 0.6 inches, 0.7 inches, 0.8 inches, 0.9 inches, 1 inch, 1.5 inches, 2 inches, 5 inches, and/or any other or intermediate length. In some embodiments, the core can have

a radius, measured from the axis **255** of approximately 0.01 inches, 0.02 inches, 0.03 inches, 0.04 inches, 0.05 inches, 0.06 inches, 0.07 inches, 0.08 inches, 0.09 inches, 0.098 inches, 0.1 inches, 0.15 inches, 0.2 inches, 0.5 inches, and/or any other or intermediate radius.

The charging coil **250** can further include a plurality of windings **258** around the core **252**. The windings **258** can, together with the core **252**, allow charging coil **250** to magnetically couple with charger **116** to recharge the energy storage features of the implantable pulse generator **104**. In some embodiments, the windings **258** can be made by looping wire **260**, which wire **260** can be any type of wire including, for example, a litz wire, and which can be any material having desired properties, and specifically can be a metal wire, one or more times around core **252**. In some embodiments, the windings **258** can comprise any desired number of loops of wire, and can, for example, comprise 2 loops, 5 loops, 10 loops, 15 loops, 20 loops, 25 loops, 29 loops, 30 loops, 35 loops, 40 loops, 50 loops 100 loops, 200 loops, 1,000 loops, and/or any other or intermediate number of loops.

In some embodiments, and as depicted in FIG. **6**, the wire **260** can be looped around core **252** so as to create a plurality of layers of loops at different radial distances from axis **255**. As specifically depicted in FIG. **6**, a first layer of loops **257** is positioned so as to contact core **252** and to be a first radial distance from axis **255**, and a second layer of loops **259** is positioned so as to contact the first layer of loops **257** and be a second radial distance from axis **255**. In some embodiments, the first layer of loops **257** can comprise 1 loop, 2 loops, 5 loops, 10 loops, 12 loops, 13 loops, 15 loops, 16 loops, 18 loops, 20 loops, 30 loops, 50 loops, 100 loops, and/or any other or intermediate number of loops, and the second layer of loops **259** can comprise 1 loop, 2 loops, 5 loops, 10 loops, 12 loops, 13 loops, 15 loops, 16 loops, 18 loops, 20 loops, 30 loops, 50 loops, 100 loops, and/or any other or intermediate number of loops. In the embodiment depicted in FIG. **6**, the first radial distance is less than the second radial distance, and thus the radius of the loops of the first layer of loops **257** is less than the radius of the loops of the second layer of loops **259**.

The charging coil **250** can include a capacitor **262**. The capacitor **262** can comprise a variety of shapes and sizes and can have a variety of electrical properties. In some embodiments, for example, the capacitor **262** can comprise a high Q capacitor and in some embodiments, can be a high Q COG capacitor.

The capacitor **262** can, in connection with windings **258**, create a tank circuit. In some embodiments, this tank circuit can be a high Q tank circuit. In some embodiments, for example, the Q factor of the high Q tank circuit can be, for example, at least 10, at least 20, at least 30, at least 40, at least 50, at least 60, at least 70, at least 80, at least 100, at least 120, at least 200, and/or any other or intermediate value. The tank circuit can increase the Q factor of the charging coil **250**. This Q factor of the charging coil **250** increases as the distance between the windings **258** and the capacitor **262** decreases. Thus, in some embodiments, the capacitor can, and as shown in FIG. **6**, be placed on the windings **258**, and in some embodiments, the capacitor **262** can be placed in proximity to the windings **258** such as, for example, a distance of less than 5 cm from the windings **258**, less than 4 cm from the windings **258**, less than 3 cm from the windings **258**, less than 2 cm from the windings **258**, less than 1 cm from the windings **258**, less than 0.5 cm from the windings **258**, less than 0.1 cm from the windings **258**, and/or any other or intermediate distance from the windings **258**.

The charging coil **250** can include a first lead **264** and a second lead **266**. The first and second leads **264**, **266** can be used to electrically connect the charging coil **250** to other features and/or components of the implantable pulse generator **104**. In some embodiments, the leads **264**, **266** can extend from the capacitor **262**, and in some embodiments, the leads **264**, **266** can extend from the windings **258**.

With reference now to FIG. **7**, a perspective view of one embodiment of a charging coil **350** that can be used in a charger is shown. The charging coil **350** can comprise a variety of shapes and sizes and can be made of a variety of materials. In some embodiments, the charging coil **350** can comprise a solenoid. In some embodiments, the charging coil **350** can be sized and shaped so as to fit within the charger **116**, and specifically within the charge head **144** of the charger **116**. In some embodiments, the charging coil **350** can be configured to magnetically couple with features of the implantable pulse generator **104** such as, for example, the charging coil **250** of the implantable pulse generator **104** to recharge the one or several energy storage features of the implantable pulse generator **104**.

In some embodiments, and to facilitate the magnetic coupling of the charging coil **350** of the charger **116** with the charging coil **250** of the implantable pulse generator **104**, the charging coil **350** of the charger **116** can have a high Q factor. In some embodiments, for example, the Q factor of the charging coil **350** can be, for example, at least 50, at least 100, at least 150, at least 200, at least 250, at least 250, at least 350, at least 350, at least 450, at least 500, at least 1,000, and/or any other or intermediate value.

The charging coil **350** can include a core **352**. The core **352** can comprise a variety of shapes and sizes and can be made from a variety of materials. In some embodiments, the core **352** can be sized and shaped to facilitate the wrapping of one or several wires around the core **352** and/or the core **352** can be sized and shaped to achieve and/or facilitate in achieving a desired Q factor for the charging coil **350**. In some embodiments, the core **352** can comprise a metal core and/or a ferritic core, and in some embodiments, the core **352** can comprise a soft ferritic core.

In some embodiments, and as shown in FIG. **7**, the core **352** can comprise an elongate member, and can specifically comprise an elongate rectangular member that can have first end **354** and a second end **356**. As seem in FIG. **7**, an axis **357**, which can be a longitudinal axis, can extend along the centerline of the core **352** between the first end **354** and the second end **356**, and the length of the core **352** can be measured and/or defined with respect to this axis **357**.

The core **352** can comprise a first foot **358** and/or a second foot **360**. In some embodiments, the first foot **358** can be located at and/or proximate to the first end **354** and the second foot **360** can be located at and/or proximate to the second end **356**. In some embodiments, the first and second feet **358**, **360** extend away from the axis **357**, and in some embodiments, the first and second feet **358**, **360** extend in the same direction and to the same extent away from the axis **357**. In some embodiments, the first and second feet **358**, **360** can be configured for sliding engagement with other components of the charger **116**, and specifically with other components of the charge head **144**. The first and second feet **358**, **360** can, in some embodiments, be made of the same material as the core **352**, and in some embodiments, the feet **358**, **360** can be made of a different material than the core **352**.

The charging coil **350** can further include a plurality of windings **362** around the core **352**. The windings **362** can, together with the core **352** allow charging coil **350** to magnetically couple with implantable pulse generator **104** to

recharge the energy storage features of the implantable pulse generator **104**. In some embodiments, the windings **362** can be made by looping wire **364**, which wire **364** can be any type of wire including, for example, a litz wire, and which can be any material having desired properties, and specifically can be a metal wire, one or more times around core **352**. In some embodiments, the windings **362** can comprise any desired number of loops of wire, and can, for example, comprise 2 loops, 5 loops, 10 loops, 15 loops, 20 loops, 25 loops, 29 loops, 30 loops, 35 loops, 40 loops, 50 loops 100 loops, 200 loops, 1,000 loops, and/or any other or intermediate number of loops. In some embodiments, the windings **362** can be exposed, and in some embodiments, the windings **362** can be covered by, for example, tape such as a mylar tape.

In some embodiments, although not depicted in FIG. **7**, the wire **364** can be looped around core **352** so as to create a plurality of layers of loops at different radial distances from axis **357**. Specifically a first layer of loops can be positioned so as to contact core **352** and to be a first radial distance from axis **357**, and a second layer of loops can be positioned so as to contact the first layer of loops and be a second radial distance from axis **357**. In such an embodiment, the first radial distance can be less than the second radial distance, and thus the volume encompassed by the loops of the first layer of loops can be less than the volume encompassed by the loops of the second layer of loops.

The charging coil **350** can include a first lead **366** and a second lead **368**. The first and second leads **366**, **368** can be used to electrically connect the charging coil **350** to other features and/or components of the charger **116**. In some embodiments, the leads **366**, **368** can be the ends of wire **364**, and in some embodiments, the leads **366**, **368** can be connected to the ends of wire **364**.

With reference now to FIG. **8**, a flowchart illustrating one embodiment of a process **500** for providing an alignment indicator for a charger **116** is shown. The process **500** can be performed by one or several of the components of the implantable neurostimulation system **100**, and in some embodiments, can be performed by the charger **116**. In some embodiments, the process **500** can be performed by some or all of the components of the charger **116** including, for example, the network interface **350**, the indicator control module **352**, and/or the charging module **354**. The process **500** can be performed as part of recharging, and can be specifically performed to facilitate in the positioning and/or orienting of the charger **116** with respect to the implantable pulse generator **104**. The process **500** can facilitate in positioning and/or orienting of the charger **116** through the control of one or several indicators which can provide information to the user regarding the effectiveness of a charging field at the implantable pulse generator **104**, which effectiveness can vary, at least in part, based on the positioning and/or orienting of the charger **116** with respect to the implantable pulse generator **104**.

The process **500** begins at block **502** wherein the charging coil of the charger **116** is operated at a first power level. In some embodiments, this first power level can describe the power of the charging field generated by the charging coil of the charger **116**. This first power level can be obtained by controlling, for example, one or both of the voltage of the charging coil of the charger **116** and the current of the charging coil of the charger **116**. In some embodiments, this first power level can be a zero power level, in which no charging field is generated, and in some embodiments, this first power level can be a non-zero power level, in which a charging field is generated. In some embodiments, the charging coil can be operated at the first level based on controls received from, for example, the charging module **354** of the charger **116**.

After the charging coil is set to the first level, the process **500** proceeds to block **504**, wherein a signal is received from a charged device. In some embodiments, the signal can be received via the network interface **350** of the charger **116**. The signal can be received from the charged device, which can be the implantable pulse generator **104** via network **110**, and specifically, can be received from the network interface **300** of the implantable pulse generator **104**. In some embodiments, the signal can be analyzed by the processor of the charger **116**. In some embodiments, the signal can be received at a discrete time, and in some embodiments, the signal can be repeatedly and/or continuously received during the performing of steps **506-514**. In some such embodiments, process **500** can become a dynamic process in that many of steps **506-514** are simultaneously performed as the signal is repeatedly and/or continuously received.

The signal can include information relating to a parameter of the implantable pulse generator **104**, and specifically to a parameter identifying the effect of the charging field on the implantable pulse generator **104**. This parameter can, for example, identify the voltage induced by the charging field at the charging coil of the implantable pulse generator **104**, identify the current induced by the charging field at the charging coil of the implantable pulse generator **104**, identify a temperature of the implantable pulse generator **104**, of a component of the implantable pulse generator **104**, or of surrounding tissue, identify a charge state of the energy storage features of the implantable pulse generator **104**, or the like.

After the signal received from the charged device has been received, the process **500** proceeds to block **506**, wherein the signal is compared to one or several charging criteria. In some embodiments, these criteria can relate to whether and to what degree the charging field is charging the energy storage feature of the implantable pulse generator **104**. These criteria can relate to, for example, whether the charging field is detectable at the implantable pulse generator **104**, the voltage induced by the charging field in the charging coil of the implantable pulse generator **104**, the current induced by the charging field in the charging coil of the implantable pulse generator **104**, the charge state of the energy storage features of the implantable pulse generator **104**, the temperature of the implantable pulse generator **104** or components thereof, or the like. In some embodiments, the comparison of the signal to the criteria can include a determination of whether the charging field allows safe charging of the implantable pulse generator **104** and the degree to which the charging field allows effective charging of the implantable pulse generator **104** such as, for example, whether the measured parameter (induced voltage, induced current, temperature, temp delta, etc. . . . falls within an acceptable range).

After the signal has been compared to the charging criteria, the process **500** proceeds to decision state **508**, wherein it is determined if the charge coil level should be adjusted. In some embodiments, this can include, for example, increasing the level of the charging field if the charging field strength is inadequate, decreasing the level of the charging field if the charging field strength is too high, or the like. In some embodiments, this can further include determining that adjustment to the position and/or orientation of the charger **116** with respect to the implantable pulse generator **104** is desirable to increase the effectiveness of the charging field.

If it is determined that the coil level is to be adjusted, then the process **500** proceeds to block **510**, wherein the coil level is adjusted. In some embodiments, this can include, for

example, incrementing or decrementing the coil level to the next one of several discrete levels, or increasing the coil level by a predetermined value.

Returning again to decision state **508**, if it is determined that the coil level should not be adjusted, then the process **500** proceeds to block **512**, wherein the indicator, which can be an alignment indicator is activated. In some embodiments, in which the signal is repeatedly and/or continuously received, the indicator can be controlled to reflect the change of charging field effectiveness as represented by the signal over a period of time. Thus, in such an embodiment, if the effectiveness of the charging field increases, which can be due to, for example, the repositioning and/or reorienting of the charger **116**, the indicator can be controlled to reflect this increased effectiveness. Similarly, if the effectiveness of the charging field decreases, which can be due to, for example, the repositioning and/or reorienting of the charger **116**, the indicator can be controlled to reflect this decreased effectiveness.

With reference now to FIG. **9**, a flowchart illustrating one embodiment of a process **600** for providing an alignment indicator for a charger based on detected variations in measured voltage and current is shown. The process **600** can be performed by one or several of the components of the implantable neurostimulation system **100**, and in some embodiments, can be performed by the charger **116**. In some embodiments, the process **600** can be performed by some or all of the components of the charger **116** including, for example, the network interface **350**, the indicator control module **352**, and/or the charging module **354**. The process **600** can be performed as part of recharging, and can be specifically performed to facilitate in the positioning of the charger **116** with respect to the implantable pulse generator **104**. The process **600** can facilitate in positioning of the charger **116** through the control of one or several indicators which can provide information to the user regarding the effectiveness of a charging field at the implantable pulse generator **104**, which effectiveness can vary, at least in part, based on the positioning of the charger **116** with respect to the implantable pulse generator **104**.

The process **600** begins at block **602** wherein the charger **116** is powered. In some embodiments, the powering of the charger **116** can correspond to a user turning the charger **116** on, or to selecting a charging mode of operation. After the charger is powered, the process **600** proceeds to block **604**, wherein the charging coil is set to and/or operated at an initial level. In some embodiments, this initial level can describe the power of the charging field generated by the charging coil of the charger **116**. This initial level can be obtained by controlling, for example, one or both of the voltage of the charging coil of the charger **116** and the current of the charging coil of the charger **116**. In some embodiments, this initial level can be a zero power level, in which no charging field is generated, and in some embodiments, this initial level can be a non-zero power level, in which a charging field is generated. In some embodiments, the charging coil can be operated at the initial level based on controls received from, for example, the charging module **354** of the charger **116**.

After the charging coil is set to an initial level, the process **600** proceeds to block **606**, wherein communication between the implantable pulse generator **104** and the charger **116** is established. In some embodiments, this can include, for example, the charger **116** initiating communication by sending a query to the implantable pulse generator **104**, and the implantable pulse generator **104** responding to the query of the charger **116**.

After communication between the implantable pulse generator **104** and the charger **116** has been established, process **600** proceeds to decision state **608**, wherein the communication link between the implantable pulse generator **104** and the charger is confirmed. If it is determined that communication has not been established, then the process **600** proceeds to block **610**, wherein the event is logged in, for example, the memory of the charger, and the process **600** then proceeds to block **612**, wherein the failure is indicated. In some embodiments, this indication can identify a specific failure, in this case, for example, a failure to establish communication between the implantable pulse generator **104** and the charger **116** is indicated, and in some embodiments, the indication of the failure can be generic.

Returning again to decision state **608**, if it is determined that communication has been established, then the process **600** proceeds to block **614**, wherein the indicators are activated. In some embodiments, this can include powering the indicators. After the indicators have been activated, the process **600** proceeds to block **616** wherein the coil level of the charging coil of the charger **116** is increased. After the coil level of the charging coil of the charger **116** has been increased, the process **600** proceeds to decision state **618**, wherein it is determined if the charging coil is operating at its maximum level, and specifically if a preset upper limit has been reached. This determination can be made by identifying the present level of the charging coil and comparing the present level of the charging coil to the maximum possible level of the charging coil. If the present level of the charging coil is less than the maximum level of the charging coil, then the charging coil is not operating at its maximum level. Alternatively, if the present level of the charging coil is equal to the maximum level, then the charging coil is operating at the maximum level.

If it is determined that the charging coil is not operating at its maximum level, then the process **600** proceeds to decision state **620**, wherein it is determined if the charging field is detected at the charged device, and specifically, if the charging field is detectable at the implantable pulse generator **104**. In some embodiments, this determination can be made based on information that can be received, via a signal or via a communication from the implantable pulse generator **104**. In some embodiments, this information can include data relating to one or several parameters, identifying the effect of the charging field on the implantable pulse generator **104**. If it is determined, based on this data, that the charging field is not detectable at the charged device, then the process **600** returns to block **616**, and proceeds as outlined above.

If it is determined that the charging field is detected at the charged device, then the process **600** proceeds to decision state **622**, wherein it is determined if the charging field, as measured at the implantable pulse generator, is too strong, or alternatively, if the charging field is at an acceptable strength level. In some embodiments, an acceptable strength level can be a level at which the implantable pulse generator is capable of recharging the energy storage features. In some embodiments, this can be determined by comparing a current property of the energy storage features, such as, for example, the voltage of the energy storage features with a parameter of the charging field, such as, for example, the voltage induced by the charging field at the charging coil of the implantable pulse generator **104**. In some embodiments, an acceptable strength level can be a level at which the implantable pulse generator is capable or recharging the energy storage features and an acceptable rate or within an acceptable time range.

In some embodiments, the acceptability of the strength level of the charging field can be determined by determining whether the charging field is causing excessive heating of the implantable pulse generator **104** or one or several compo-

nents thereof, or if the strength of the charging field is resulting in the induction of undesirable current levels at the charging coil of the implantable pulse generator **104**. In one embodiment, for example, this can be determined by measuring the current passing through the shunt circuit. In some embodiments, the shunt circuit can be any circuit that can dispose of or channel excess current generated by the charging field. If this current exceeds a threshold value, then the strength of the charging field may be too high. Similarly, if the temperature of the implantable pulse generator, or one or several components thereof exceeds a threshold temperature, then the strength of the charging field may be too high.

If it is determined that the charging field is too strong, then the process **600** proceeds to block **624**, wherein the coil level is decreased. After the coil level has been decreased, the process **600** returns to decision state **622** and proceeds as outlined above.

Returning again to decision state **618**, if it is determined that the charging coil has reached its maximum level, or returning again to decision state **622**, if it is determined that the charging field is not too strong, then process **600** proceeds to decision state **626**, wherein it is determined if the charging field is detected at the charged device, and specifically, if the charging field is detectable at the implantable pulse generator **104**. In some embodiments, this decision state can replicate the determination of decision state **620**. In such an embodiment, this determination can be made based on information that can be received, via a signal or via a communication from the implantable pulse generator **104**. In some embodiments, this information can include data relating to one or several parameters, identifying the effect of the charging field on the implantable pulse generator **104**. If it is determined, based on this data, that the charging field is not detected, then the process **600** proceeds to block **610** wherein the event is logged in, for example, the memory of the charger, and the process **600** then proceeds to block **612**, wherein the failure is indicated. In some embodiments, this indication can identify a specific failure, in this case, for example, a failure create a charging field detectable at the implantable pulse generator **104** is indicated, and in some embodiments, the indication of the failure can be generic.

Returning again to decision state **626**, if it is determined that the charging field is detected, then the process **600** proceeds to decision state **628** wherein it is determined if there is a change in the voltage induced by the charging field at the charging coil of the implantable pulse generator **104** The determination of decision state **628** can be based on data contained in one or several signals received from the implantable pulse generator **104** during the performance of the process **600**.

In some embodiments, decision state **628** can, in connection with decision state **630** be used to determine whether the effectiveness of the charging field at the charging coil of the implantable pulse generator **104** is increasing or decreasing. In some embodiments, these changes to the effectiveness of the charge coil can be caused by the movement and/or repositioning and/or reorienting of the charger **116** with respect to the implantable pulse generator **104**. In some embodiments the advancement of process **600** to decision state **628** can be delayed until a predetermined time interval has passed, and can be preceded by the activation of an indicator directing the user to reposition the charger **116**. In such an embodiment, this can result in comparing the effectiveness of the charging field at a first time to the effectiveness of the charging field at a second time. In some embodiments, this can result in determining an effectiveness of the charging field at a first time based on a first signal, and determining the effectiveness of the charging field at a second time based on a second signal. In some embodiments, this can be repeated until a desired and/or maximum effectiveness level is identified, and in some embodiments, this can be repeated until a pre-determined amount of time has passed.

If it is determined that there is no change in the voltage induced by the charging field at the charging coil of the implantable pulse generator **104**, then the process **600** proceeds to decisions state **630**, wherein it is determined if there is a change in the current induced by the charging field at the charging coil of the implantable pulse generator **104**. In some embodiments, this change in current induced by the charging field at the charging coil of the implantable pulse generator **104** can be based on data received at the charger **116** from the implantable pulse generator **104**, which data can identify, for example, changes to the current flowing through the shunt circuit of the implantable pulse generator **104**.

If it is determined that the current induced by the charging field at the charging coil of the implantable pulse generator **104** is higher at decisions state **630**, as compared to the previous current induced by the charging field at the charging coil of the implantable pulse generator, or if it is determined that the voltage induced by the charging field at the charging coil of the implantable pulse generator **104** is higher at decision state **628**, as compared to the previous voltage induced by the charging field at the charging coil of the implantable pulse generator, then the process **600** proceeds to block **632**, wherein the indicators are controlled to indicate the increased voltage or current. In some embodiments, this can likewise indicate an increased effectiveness of the charging field at the charging coil of the implantable pulse generator **104**.

Returning again to decision state **630**, if it is determined that the current induced by the charging field at the charging coil of the implantable pulse generator **104** is lower at decisions state **530**, as compared to the previous current induced by the charging field at the charging coil of the implantable pulse generator, or if it is determined that the voltage induced by the charging field at the charging coil of the implantable pulse generator **104** is lower at decision state **628**, as compared to the previous voltage induced by the charging field at the charging coil of the implantable pulse generator, then the process **600** proceeds to block **634**, wherein the indicators are controlled to indicate the decreased voltage or current. In some embodiments, this can likewise indicate an decreased effectiveness of the charging field at the charging coil of the implantable pulse generator **104**.

After the indicators have been adjusted as in either block **632** or block **634**, or returning again to decision state **630**, if it is determined that there has been no change in the current induced by the charging field, the process **600** proceeds to decision state **636**, wherein it is determined whether to continue process **600**. In some embodiments, this can include, for example, determining whether a predetermined amount of time has passed, after which the process **600** should be terminated. In some embodiments, decision state **636** can include determining whether the effectiveness of the charging field has reached a maximum value, or exceeded an effectiveness threshold. If it is determined that process **600** should not be continued, then process **600** proceeds to block **638** and terminates. If it is determined that process **600** should continue, process **600** returns to decision state **628** and proceeds as outlined above. In some embodiments, the process **600** can be performed and/or repeated at any desired rate. In some embodiments, for example, process **600** can be performed and/or repeated 1,000 times per second, 500 times per second, 200 times per second, 100 times per second, 50 times per second, 25 times per second, 10 times per second, 5 times per

second, 2 times per second, 1 times per second, 30 times per minutes, 20 times per minute, 10 times per minute, 5 times per minute, 1 time per minute, 30 times per hour, 20 times per hour, 10 times per hour, 5 times per hour, 1 time per hour, and/or any other or intermediate rate.

With reference now to FIG. **10**, a flowchart illustrating one embodiment of a process **700** in which movement of a charger is detected during the charging is shown. In some embodiments, the process **700** can be performed during the charging of the implantable pulse generator **104** to detect movement of the charger **116** with respect to the implantable pulse generator **104**. The process can be performed by the implantable pulse generator **104**, the charger **116**, and/or any other components of the implantable neurostimulation system **100**. The process **700** can be performed during the charging of the implantable pulse generator **104**. In some embodiments, the process **700** can be continuously performed during the charging of the implantable pulse generator **104**, and in some embodiments, the process **700** can be periodically performed during the charging of the implantable pulse generator.

The process **700** begins at block **702**, wherein charge data is received by the charger **116** from a charged device, which can be, for example, the implantable pulse generator **104**. In some embodiments, this charge data can include information identifying the charge state of the energy storage features of the implantable pulse generator **104**, and in some embodiments, this information can identify whether the charging of the implantable pulse generator **104** is complete. This information can be received by the network interface **350** of the implantable pulse generator **104** from the network interface **300** of the implantable pulse generator **104**.

After the charge data has been received, the process **700** proceeds to decision state **704**, wherein it is determined if the charging of the implantable pulse generator **104** is complete. In some embodiments, this determination can be made based on the charge data received in block **702**, which data can include information identifying the charge state of the energy storage features of the implantable pulse generator **104**, and/or whether the charging of the implantable pulse generator **104** is complete. If it is determined that the charging is complete, then process **700** proceeds to bock **706**, wherein the charging coil of the charger **116** is turned off.

Returning again to decision state **704**, if it is determined that charging is not complete, process **700** proceeds to decision state **708**, wherein temperature data contained in the received charge data is evaluated to determine if the temperature of the implantable pulse generator **104** or component thereof is too high. In some embodiments, the temperature data can identify the temperature of the implantable pulse generator **104** and/or of one or several components of the implantable pulse generator **104**. The temperature data can be evaluated to determine whether the temperature of the implantable pulse generator **104**, or of one or several components thereof, is too high. In some embodiments, this can include determining if the temperature of the implantable pulse generator **104** or of one or several components thereof is higher than a threshold value, which threshold value can be stored in memory of the implantable neurostimulation system **100**. In some embodiments, the process **700** can, in decision state **708**, determine if the temperature of the implantable pulse generator **104** or a component thereof is above a first threshold, which can be indicative of a temperature that is too high, but is at dangerous levels.

If it is determined that the temperature is too high, then the process **700** proceeds to decision state **710**, wherein it is determined if the temperature of the implantable pulse generator **104** or component thereof is an extreme temperature. This determination can be based on temperature data received as part of the charge data in block **702**.

In some embodiments, an extreme temperature can be a temperature at a dangerous level. In some embodiments, the difference between a temperature that is too high and an extreme temperature can be found in how each temperature is resolved. Thus, in some embodiments, a temperature that is too high may be resolved by decreasing the level of the charging field, whereas an extreme temperature is resolved by stopping charging.

If it is determined that the implantable pulse generator **104** or component thereof has reached an extreme temperature, then the process **700** proceeds to block **712**, wherein the charging coil of the charger **116** is turned off. If it is determined that the implantable pulse generator **104** or component thereof has not reached an extreme temperature, then the process proceeds to decision state **714**, wherein it is determined if the charging coil of the charger **116** is operating at its minimum level, which can be, for example, a preset lower limit. This determination can be made by identifying the present level of the charging coil and comparing the present level of the charging coil to the minimum possible level of the charging coil. If the present level of the charging coil is greater than the minimum level of the charging coil, then the charging coil is not operating at its minimum level. Alternatively, if the present level of the charging coil is equal to the minimum level, then the charging coil is operating at the minimum level.

If it is determined that the charging coil of the charger **116** is operating at its minimum level, then the process **700** proceeds to block **712**, wherein the charging coil of the charger **116** is turned off. If it is determined that the charging coil of the charger **116** is not operating at its minimum level, then the process **700** proceeds to decision state **716**, wherein it is determined if the implantable pulse generator **104** is charging. In some embodiments, this determination can comprise a binary determination of whether charging is occurring or not, and in some embodiments, this determination can comprise a qualification of the degree to which charging is occurring. In one specific embodiment, decision state **716** can include determining if charging is occurring and qualifying the degree to which charging is occurring. In this embodiment, decision state **716** can further include estimating the degree to which the coil level of the charging coil of the charger **116** can be decreased without ending charging and/or the degree to which a decrease in the coil level of the charging coil of the charger will impact the effectiveness of the charging field. If it is determined that the implantable pulse generator **104** is not charging, then the process **700** proceeds to block **712**, wherein the charging coil of the charger **116** is turned off.

If it is determined that the implantable pulse generator **104** is charging, then the process **700** proceeds to block **718**, wherein the level of the charging coil of the charger **116** is decreased. After the level of the charging coil of the charger **116** has been decreased, the process **700** proceeds to block **712**, wherein the charging coil of the charger **116** is turned off.

Returning again to decision state **708**, if it is determined that the temperature of the implantable pulse generator **104** or component thereof is not too high, then the process **700** proceeds to decision state **720**, wherein it is determined if the implantable pulse generator **104** is charging. In some embodiments, this determination can comprise a binary determination of whether charging is occurring or not, and in some embodiments, this determination can comprise a qualification of the degree to which charging is occurring.

In some embodiments, the determination of decision state **720** can comprise a binary determination of whether charging

is occurring or not, and in some embodiments, this determination can comprise a qualification of the degree to which charging is occurring. In one specific embodiment, decision state **716** can include determining if charging is occurring and qualifying the degree to which charging is occurring. In this embodiment, decision state **716** can further include estimating the degree to which the coil level of the charging coil of the charger **116** can be decreased without ending charging and/or the degree to which a decrease in the coil level of the charging coil of the charger will impact the effectiveness of the charging field.

If it is determined that the implantable pulse generator **104** is charging, then the process **700** returns to block **702** and proceeds as outlined above. In some embodiments, the return to block **702** can further include waiting a predetermined period of time before additional charge data is received, or before received charge data is analyzed.

If it is determined that the implantable pulse generator **104** is not charging, then the process **700** proceeds to decision state **722**, wherein it is determined if the charging coil of the charger **116** is operating at its maximum level, which can be, for example, a preset upper limit. This determination can be made by identifying the present level of the charging coil and comparing the present level of the charging coil to the maximum possible level of the charging coil. If the present level of the charging coil is less than the maximum level of the charging coil, then the charging coil is not operating at its maximum level. Alternatively, if the present level of the charging coil is equal to the maximum level, then the charging coil is operating at the maximum level.

If it is determined that the charger **116** is operating at the maximum coil level, then process **700** proceeds to block **724**, wherein the indicators are controlled to direct the user to reposition the charger **116** and/or to indicate the charger **116** has moved from its original position. After the indicators have been controlled, the process **700** can return to block **702** and proceed as outlined above. In some embodiments, and before returning to block **702**, the process **700** proceeds to decision state **628** of process **600** in FIG. **9**, and proceeds as outlined therein. In such an embodiment, after termination is indicated in block **638**, process **700** would then return to block **702** and proceed as outlined above.

Returning now to decision state **722**, if it is determined that the charge level of the charging coil of the charger **116** is not operating at a maximum level, the process **700** proceeds to block **726**, wherein the coil level of the charging coil of the charger **116** is increased. After the coil level of the charging coil of the charger **116** has been increased, the process **700** proceeds to block **724** and continues as outlined above.

In the foregoing specification, the invention is described with reference to specific embodiments thereof, but those skilled in the art will recognize that the invention is not limited thereto. Various features and aspects of the above-described invention can be used individually or jointly. Further, the invention can be utilized in any number of environments and applications beyond those described herein without departing from the broader spirit and scope of the specification. The specification and drawings are, accordingly, to be regarded as illustrative rather than restrictive. It will be recognized that the terms "comprising," "including," and "having," as used herein, are specifically intended to be read as open-ended terms of art.

What is claimed is:

1. A portable charger device for transcutaneous charging of an implantable neurostimulator in a patient, the charger device comprising:

a housing having an external surface that is configured to at least partially engage a skin surface of the patient and be positioned at least partially over the implantable neurostimulator;

an antenna disposed within the housing;

a charging coil disposed within the housing and configured to magnetically couple with a corresponding receiving coil of the implantable neurostimulator,

an indicator disposed on the housing and configured to identify an effectiveness of a charging field created between the charging coil of the charger device and the corresponding receiving coil of the implantable neurostimulator; and

a processor disposed within the housing and configured to:

set a power of the charging coil of the charger device to a first level;

generate and send a request to establish communication via the antenna;

activate the indicator to identify the effectiveness of the charging field;

increase the power of the charging coil of the charger device to a second level;

determine if the power of the charging coil at the second level is at a maximum level;

receive a first signal from the implantable neurostimulator at a first time;

determine if the charging field generated by the charging coil of the charger device at the second level is detectable at the corresponding receiving coil of the implantable neurostimulator;

determine a current flowing through a shunt circuit of the implantable neurostimulator, wherein the current flowing through the shunt circuit is excess current generated by the charging field at the corresponding receiving coil of the implantable neurostimulator;

adjust the power of the charging coil of the charger device to a third level based in part on if the charging field is detectable at the corresponding receiving coil of the implantable neurostimulator and the determined current flowing through the shunt circuit;

receive a second signal from the implantable neurostimulator at a second time;

determine a change in the voltage induced by the charging field from the first time to the second time based on the first and second signals; and

control the indicator to indicate the change in the voltage induced by the charging field from the first time to the second time.

2. The portable charger device of claim **1**, wherein it is determined if the charging field generated by the charging coil at the second level is detectable based on data contained in the first signal.

3. The portable charger device of claim **2**, wherein determining if the power of the charging coil at the second level is at the maximum level comprises:

comparing the second level to the maximum level; and

identifying that the power of the charging coil at the second level is at the maximum level if the second level is greater than or equal to the maximum level.

4. The portable charger device of claim **3**, wherein the processor is further configured to determine based on the received signal if the charging field is at an acceptable strength level if the charging field is detectable at the corresponding receiving coil of the implantable neurostimulator.

5. The portable charger device of claim **4**, wherein determining if the charging field is at an acceptable strength level comprises determining at least one of: if the voltage induced

by the charging field is adequate to charge the implantable neurostimulator within a time range, and if a current flowing through the shunt circuit exceeds a threshold value.

6. The portable charger device of claim **5**, wherein the processor is further configured to control the indicator to indicate repositioning of the charger device.

7. The portable charger device of claim **6**, wherein adjusting the level of the charge field to a third level comprises at least one of: increasing the strength of the charging field if the voltage induced by the charging field is inadequate to charge the implantable neurostimulator within the time range; and decreasing the strength of the charging field if the current flowing through the shunt circuit exceeds the threshold value.

8. The portable charger device of claim **7**, wherein the processor is further configured to determine a change in the current induced by the charging field from the first time to the second time based on the first and second signals if the voltage induced by the charging field does not change from the first time to the second time; and control the indicator to indicate the change in the current induced by the charging field from the first time to the second time.

9. The portable charger device of claim **8**, wherein the first level of the power of the charging coil is a zero-level.

10. A method of controlling transcutaneous charging of an implantable neurostimulator in a patient with a charger device, wherein the charger device at least partially engages a skin surface of the patient and is positioned at least partially over the implantable neurostimulator, the charger device comprising an antenna and a charging coil configured to magnetically couple with a corresponding receiving coil of the implantable neurostimulator, the method comprising:

setting a power of the charging coil of the charger device to a first level;

generating and sending a request to establish communication via the antenna;

activating an indicator of the charger device to identify an effectiveness of a charging field created between the charging coil of the charger device and the corresponding receiving coil of the implantable neurostimulator, wherein the indicator is configured to identify the effectiveness of the charging field;

increasing the power of the charging coil to a second level;

determining if the power of the charging coil at the second level is at a maximum level;

receiving a first signal from the implantable neurostimulator at a first time;

determining if the charging field generated by the charging coil at the second level is detectable at the corresponding receiving coil of the implantable neurostimulator;

determining a current flowing through a shunt circuit of the implantable neurostimulator;

adjusting the level of the charge field to a third level based in part on if the charging field is detectable at the corresponding receiving coil of the implantable neurostimulator and the determined current flowing through the shunt circuit;

receiving a second signal from the implantable neurostimulator at a second time;

determining a change in the voltage induced by the charging field from the first time to the second time based on the first and second signals; and

controlling the indicator to indicate the change in the voltage induced by the charging field from the first time to the second time.

11. The method of claim **10**, wherein it is determined if the charging field generated by the charging coil at the second level is detectable based on data contained in the first signal.

12. The method of claim **11**, wherein determining if the power of the charging coil at the second level is at the maximum level comprises:

comparing the second level to the maximum level; and

identifying that the power of the charging coil at the second level is at the maximum level if the second level is greater than or equal to the maximum level.

13. The method of claim **12**, further comprising determining based on the received signal if the charging field is at an acceptable strength level if the charging field is detectable at the corresponding receiving coil of the implantable neurostimulator.

14. The method of claim **13**, wherein determining if the charging field is at an acceptable strength level comprises determining one of: if the voltage induced by the charging field is adequate to charge the implantable neurostimulator within a time range, and if a current flowing through the shunt circuit exceeds a threshold value.

15. The method of claim **14**, wherein adjusting the level of the charge field to a third level comprises one of: increasing the strength of the charging field if the voltage induced by the charging field is inadequate to charge the implantable neurostimulator within the time range; and decreasing the strength of the charging field if the current flowing through the shunt circuit exceeds the threshold value.

16. The method of claim **15**, further comprising determining a change in the current induced by the charging field from the first time to the second time based on the first and second signals if the voltage induced by the charging field does not change from the first time to the second time; and controlling the indicator to indicate the change in the current induced by the charging field from the first time to the second time.

17. The method of claim **16**, wherein the first level of the power of the charging coil is a zero-level.

18. The method of claim **17**, wherein the generating and the sending of the request to establish communication is independent of charging.

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